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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,918	11/01/2001	Sinpei Nakata	KAS-157	3025
24956	7590	07/31/2006	EXAMINER	
MATTINGLY, STANGER, MALUR & BRUNDIDGE, P.C. 1800 DIAGONAL ROAD SUITE 370 ALEXANDRIA, VA 22314			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/936,918

Applicant(s)

NAKATA ET AL.

Examiner

Lyle A. Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,6 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6 and 8-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/16/06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3,6 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The last paragraph of claim 1 is not clear what steps are intended by "... analysis parameters ... ". What types of analysis parameters are intended ? Further " ... calculates, based on the stored ..." is not clear what type of calculation steps are performed. The claims " standard value" is vague and indefinite as to what this value is and how it is calculated. The claimed "accuracy management" is also vague and indefinite as to what steps/calculations are performed. The claimed "deviation" calculation is also vague and indefinite how this calculation is made.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6 and 8-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 5-288756 or JP 4-128657.

JP 5-288756 teaches a system to automatically transferring various kinds of parameters from an automatic analyzer. The automatic analyzer is provided with a sample identifying means 3, a reagent identifying means 10, and communication means 30, 31, 32. A sample identifying code 4 and a reagent identifying code 11 are automatically read by the sample identifying means and the reagent identifying means, and transmitted to an external computer 29 by the communication means. It is so designed that a parameter related to the analysis determined by the reagent and such parameters as the concentration, calibration curve, etc., of a standard sample to be used for calibration or the like are taken into the automatic analyzer from the external computer 29.

JP 4-128657 teaches an automated analyzer coupled to a network to monitor the condition as that at the time of analysis. The output is returned to any of the devices on the network after treating the parameters to determining if the analytical conditions and the results of analysis are valid. A plurality of analytical devices 6 and 10 are connected to a computer(1) via telecommunication lines (5). The conditions for operating the analytical devices are stored in a transmission parameter table(4) of the computer (1). At the start of analysis the data is sent to their respective analytical devices. The respective analytical devices store the analytical conditions being sent at the start of analysis in the parameter tables(8) and (12), and carry out analysis under these conditions. After completion of analysis. the results of analysis and the contents of the parameter table are sent and

stored in the computer(1) automatically or by the instructions of an analyzer.

The computer(1) stores the analytical results and parameters sent by the analytical devices 6 and 10 as a set. Thus, since the control of both the analytical results and the analytical conditions is simultaneously carried out, errors can be prevented and the reliability of data can be enhanced.

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Fritchie et al.(USP 6,022,746).

See the appropriate paragraph of the 5/31/05 Office action.

In light of the above 35 USC 112 second paragraph issues, the invention is best understood as a method of monitoring reagents and their controls. The Office maintains all of these steps are performed by Fritchie et al.

### ***Response to Arguments***

Applicants' arguments filed 5/16/06 have been fully considered but they are not persuasive.

Applicant's state the claim language is easily understood by one having ordinary skill in the art and the 35 USC 112 second paragraph rejections should be vacated. The Office maintains the claimed must unambiguously describe a method that could be performed. The present claims use general terms that do not describe exact steps that could be followed by one having ordinary skill in the art.

Applicants' state the claimed terms in light of the specification define over the cited prior art. The Office maintains in light of the 35 USC 112 second paragraph issues it is not clear what steps are distinctively claimed. In the absence of clarification, the

Office maintains the cited prior art teaches the same types of general method steps and properly applied here.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander  
Primary Examiner  
Art Unit 1743



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